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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/664,380 | 09/17/2003 | Ronald P. Spinello | 1282-8CIP | 4560 |

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EXAMINER

HAN, MARK K

ART UNIT PAPER NUMBER

3767

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

10/664.380

| | |
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| Applicant(s) | |
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SPINELLO, RONALD P.

Examiner

Mark K. Han

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on *19 January 2006*.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
4a) Of the above claim(s) 30-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Species I in the replies filed on 31 August 2005 and 19 January 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 30-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the replies filed on 31 August 2005 and 19 January 2006.

Claim Objections

3. Claims 26-29 are objected to because of the following informalities: Claims 26-29 recite the limitation "said guide" in line 1 of each claim. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required. For the purposes of this Office Action, it is assumed that claims 26-29 depend from claim 25.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-4, 6, 7, 10, 11, 13 and 16-28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,974,831 to Malmin.

Malmin discloses a syringe kit having a flexible conduit 53, a needle handle 41/11, a distal bore (near reference numeral 41a), a connector 41a and a pierceable seal 28. See Figures 1-5. See is made from a rubber-like material (col. 4, lines 1-10). The seal is cylindrical, ovoid and flat. The seal is received in a recess formed by element 43a. A portion of the needle handle (21) is compressed during attachment of a double-ended needle to said needle handle. There are at least two recesses adjacent to the seal 23 and the one formed by element 43a. Malmin also discloses a guide 22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5, 8, 9, 12, 14, 15 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmin.

In reference to claims 5 and 12, Malmin discloses a seal that is ovoid in shape. Malmin, however, does not disclose expressly a rectangularly shaped seal. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to change the shape of the ovoid seal to one that is rectangular because Applicant has not disclosed that a rectangular seal provides an advantage, is used for a particular purpose, or solves

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a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with ovoid seal of Malmin because both seal provide the function of sealing the interior of the needle handle from contaminants. Therefore, it would have been an obvious matter of design choice to modify Malmin to obtain the invention as specified in claims 5 and 12.

In reference to 8, 9, 14, 15 and 29, Malmin discloses the claimed invention as shown above. Malmin, however, does not disclose the use of an adhesive to attach the seal to the needle handle. Malmin uses an interference fit. Applicant suggests the use of cyanoacrylate as the preferred adhesive. See specification p. 31, paragraph 2. Cyanoacrylate is a well-known adhesive used in many biomedical applications. It is considered well-within the skill of an ordinary artisan to use an adhesive such as cyanoacrylate to attach the seal to the needle handle instead of an interference fit. Such an alternative would be readily recognized by the artisan to be functionally equivalent.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K. Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark K. Han
Patent Examiner
Art Unit 3767

mkh
April 3, 2006

C.
KEVIN SIRMONS
PRIMARY EXAMINER

